DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 13, 2014

Prosidyan, Inc.
% Ms. Janice Hogan
Regulatory Counsel
Hogan Lovells US LLP
1835 Market Street, 29th Floor
Philadelphia, Pennsylvania 19103

Re: K141956
Trade/Device Name: FIBERGRAFT™ BG Morsels Bone Graft Substitute
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: July 18, 2014
Received: July 18, 2014

Dear Ms. Hogan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page

510(k) Number *(if known)*

K141956

Device Name

FIBERGRAFT™ BG Morsels Bone Graft Substitute

Indications for Use *(Describe)*

FIBERGRAFT™ BG Morsels Bone Graft Substitute is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. FIBERGRAFT™ BG Morsels is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process.

FIBERGRAFT™ BG Morsels is not indicated for use in load-bearing applications; therefore, standard internal or external stabilization techniques must be followed to obtain rigid stabilization.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) SUMMARY

Prosidyan, Inc.'s FIBERGRAFT™ BG Morsels Bone Graft Substitute

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Prosidyan, Inc.
30 Technology Drive
Warren, NJ 07059
Tel. 908-517-3666
Fax 908-396-1151

Contact Person: Charanpreet S. Bagga

Date Prepared: July 17, 2014

Name of Device and Name/Address of Sponsor

FIBERGRAFT™ BG Morsels Bone Graft Substitute

Common or Usual Name

Bone Void Filler

Classification Name/CFR Regulation/Product Code

Resorbable Calcium Salt Bone Void Filler, 21 CFR 888.3045, product code MQV, Class II

Predicate Devices

Prosidyan's BG Morsels Bone Graft Substitute

Purpose of the Special 510(k) notice.

The FIBERGRAFT™ BG Morsels Bone Graft Substitute is a modification to the previously cleared BG Morsels. There have been no changes to the intended use of the device or its fundamental scientific technology.

Intended Use

The FIBERGRAFT™ BG Morsels Bone Graft Substitute is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. FIBERGRAFT™ BG Morsels is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process.

FIBERGRAFT™ BG Morsels is not indicated for use in load-bearing applications; therefore, standard internal or external stabilization techniques must be followed to obtain rigid stabilization.

Technological Characteristics

FIBERGRAFT™ BG Morsels provides an osteoconductive, resorbable, biocompatible bone graft substitute made from crystalline 45S5 bioactive glass. Each granule of FIBERGRAFT™ BG Morsels is created from a matrix of bioactive glass fibers and microspheres. Bioactive glass is defined as a group of glasses which has a compositional range that allows the formation of hydroxyapatite (HA) as a surface layer when exposed to an aqueous phosphate-containing solution such as simulated body fluid. The HA layer that forms in an aqueous phosphate-containing solution plays a significant role in forming a strong bond with natural bone. The granules provide an ultra-porous scaffold for desired biological response and improved handling characteristics, while optimizing radiopacity and resorption. FIBERGRAFT™ BG Morsels are generally spherical in appearance and provided in granular form. The matrix is flash sintered to form a porous shell at its surface, which creates the generally spherical structure of the granules, while maintaining a level of porosity within each granule. The primary purpose of this submission is to add the option to use blood to mix with the product prior to implantation. Changes were also made to the product trade name and the labeled volume sizes.

Performance Data

In support of this submission, testing was conducted to compare the fluid absorbability of the product when mixed with blood compared to saline. Device packability and handling characteristics were also observed during testing. Testing was conducted at time zero and after aging. All test results were passing, supporting substantial equivalence of the modified device compared to the predicate device. No changes were made to the product composition, packaging, sterility, or biocompatibility as compared to the predicate device. The performance testing results demonstrated that the FIBERGRAFT™ BG Morsels is substantially equivalent to the predicate device.

Substantial Equivalence

The indications for use and the fundamental scientific technology of the proposed FIBERGRAFT™ BG Morsels product has not changed relative to the predicate. The FIBERGRAFT™ BG Morsels has the same intended use, indications, and technological characteristics as the previously cleared BG Morsels, and similar principles of operation. The FIBERGRAFT™ BG Morsels is manufactured using the same material, has the same shelf life, and is packaged and sterilized using the same materials and processes as the predicate, demonstrating substantial equivalence to the predicate device. Performance testing of the modified FIBERGRAFT™ BG Morsels demonstrated that the device functions as intended without raising new safety or effectiveness questions compared to the previously cleared BG Morsels.

Conclusion

The FIBERGRAFT™ BG Morsels is an osteoconductive, resorbable, biocompatible bone graft substitute composed of crystalline bioactive glass. The purpose of this Special 510(k) is to add the option to use blood as a mixing agent to the labeling. In addition, the labeled

volume sizes and the product name of the subject device have been modified since the previously cleared predicate. The verification and process qualification testing confirms that these changes meet the acceptance criteria in testing. Thus, the proposed FIBERGRAFT™ BG Morsels is substantially equivalent to its predicate.